ARNOLD & PORTER LLP



July 1, 2004

Milan M. Vinnola Milan_Vinnola@aporter.com 202.942.6111 202.942.5999 Fax

555 Twelfth Street, NW Washington, DC 20004-1206

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Art Unit: 1614 Conf. No.: 5134

Re:

U.S. Patent Application Serial No. 10/741,534 filed December 19, 2003

Inventors: Alain BARON et al.

Titles Comments on fourth

Compositions for the Treatment and Prevention of Nephropathy

Atty. Dkt: 18528.675 / 0218-UTL-9

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

- 1. Information Disclosure Statement;
- 2. Form PTO/SB08a (2 pages) and Form PTO/SB08b (2 pages), with 25 accompanying documents; and
- 3. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 18528.675. A duplicate copy of this letter is enclosed.

Sincerely,

Milan M. Vinnola (Reg. No. 45,979)

Mulan Milinda

Enclosures

PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Confirmation no.: 5134

Alain BARON et al.

Appl. No.: 10/741,534

Art Unit: 1614

Examiner: To Be Assigned

Filed: December 19, 2003

Atty. Docket: 18528.675 / 0218-UTL-9

For: Compositions for the Treatment and Prevention of Nephropathy

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The attention of the Examiner is invited to the documents listed on the attached Forms PTO-SB08a and PTO-SB08b. It is respectfully requested that the information above be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

However, Applicants make no representation or admission regarding the relevance or availability of the cited references as "prior art" to the present application.

CERTIFICATION AND/OR FEE

Because this Information Disclosure Statement is being submitted prior to the mailing date of the first action on the merits in the above-captioned application, it is believed that no fee is required. However, it if is deemed that a fee is required for submission of this Information Disclosure Statement and consideration of the attached documents, authorization is given in the accompanying transmittal letter.

Respectfully submitted,

Thomas E. Holsten (Reg. No. 46,098) Milan M. Vinnola (Reg. No. 45,979)

Date: July 1, 2004

ARNOLD & PORTER LLP

Attn: IP Docketing 555 Twelfth Street, N.W.

Washington, D.C. 20004-1206

(202) 942-5000 telephone

(202) 942-5999 facsimile

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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JUL 0 1 2004 Complete if Known Substitute for form 1449A/PTO Application Number 10/741,534 INFORMATION DISCL December 19, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Alain BARON Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** To Be Assigned 4 Sheet 1 of Attorney Docket Number 18528.675

				U.S. PATENT DO	OCUMENTS	
Examiner Initials*	Cite No. ¹		ment Number per-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US-	2002/0137666 A1	09-26-2002	Beeley et al.	
	Bl	US-	2003/0087820 A1	05-08-2003	Young et al.	
	Cl	US-	2003/0220243 A1	11-27-2003	Glaesner et al.	
	D1	US-	5,118,666	06-02-1992	Habener	
	El	US-	5,120,712	06-09-1992	Habener	
	F1	US-	5,512,549	04-30-1996	Chen et al.	
	Gl	US-	5,545,618	08-13-1996	Buckley et al.	
	Hl	US-	5,574,008	11-12-1996	Johnson et al.	
	11	US-	5,670,360	09-23-1997	Thorens	
	Jl	US-	5,705,483	01-06-1998	Galloway et al.	
	Kl	US-	5,846,747	12-08-1998	Thorens et al.	
	LI	US-	5,981,488	11-9-1999	Hoffmann	
	M1	US-	6,051,689	04-18-2000	Thorens	

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶		
	NI	EP 0 708 179 A2	04-24-1996	Eli Lilly and Company				
	01	WO 91/11457 A1	08-08-1991	Douglas I. BUCKLEY et al.				
	P1	WO 98/05351 A1	02-12-1998	Amylin Pharmaceuticals, Inc.				
	Q1	WO 98/30231 A1	07-16-1998	Amylin Pharmaceuticals, Inc.				
_	RI	WO 99/07404 A1	02-18-1999	Amylin Pharmaceuticals, Inc.				

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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		TILL O	1 100 6. I	Application Number	10/741,534	
INFORM	IATION I	DISCLO	SINE	Filing Date	December 19, 2003	
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				Art Unit	1614	
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Sheet	2	of	4	Attorney Docket Number	18528.675	

			U.S. PATENT DO	OCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A2	US- 6,268,343 B1	07-31-2001	Knudsen et al.	N
	B2	us- 6,451,974 B1	09-17-2002	Hansen	
	C2	US- 6,451,987 B1	09-17-2002	Staby	
	D2	US- 6,458,924 B2	10-01-2002	Knudsen et al.	
	E2	US- 6,514,500 B1	02-04-2003	Bridon et al.	
	F2	US- 6,528,486 B1	03-04-2003	Larsen et al.	
	G2	US- 6,569,832 B1	05-27-2003	Knudsen et al.	
	H2	US- 6,593,295 B2	07-15-2003	Bridon et al.	
	-12	US-			
	J2	US-			
	K2	US-			
	L2	US-			
	M2	US-			

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	N2	WO 99/25727 A2	05-27-1999	Amylin Pharmaceuticals, Inc.		
	O2	WO 99/25728 A1	05-27-1999	Amylin Pharmaceuticals, Inc.		
	P2	WO 01/98331 A2	12-27-2001	Eli Lilly and Company		
	Q2	WO 02/48192 A2	06-20-2002	Eli Lilly and Company		
	R2					

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Examiner	Date	i
Signature	Considered	

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	INFORM	ATION D	SOLE	SURE	Filing Date	December 19, 2003	
	STATEM	IENT BY	APPLI	ICANT	First Named Inventor	Alain BARON	
					Art Unit	1614	
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	Sheet	3	of	4	Attorney Docket Number	18528 675	

Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A3	Adelhorst et al., "Structure-Activity Studies of Glucagon-Like Peptide-1," J. Biol. Chem., 269(9):6275-6278 (1994)	
	В3	Byrne et al., "Human Studies with Glucagon-Like-Peptide-1: Potential of the Gut Hormone for Clinical Use," Diabet. Med., 13(10):854-860 (1996) (Abstract)	
	СЗ	D'Alessio et al., "Elimination of the Action of Glucagon-Like Peptide 1 Causes and Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons," J. Clin. Invest., 97(1):133-138 (1996)	
	D3	Eng et al., "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from Heloderma horridum Venom," J. Biol. Chem., 265(33):20259-20262 (1990)	
	E3	Eng et al., "Isolation and Characterization of Exendin-4, an Exendin-3 Analogue, from Heloderma suspectum Venom," J. Biol. Chem., 267(11):7402-7405 (1992)	
	F3	Hjorth et al., "Glucagon and Glucagon-Like Peptide 1: Selective Receptor Recognition via Distinct Peptide Epitopes," J. Biol. Chem., 269(48):30121-30124 (1994)	
	G3	Holz et al., "Black Widow Spider Alpha-Latrotoxin: A Presynaptic Neurotoxin that Shares Structural Homology with the Glucagon-Like Peptide-1 Family of Insulin Secretagogic Hormones," Comp. Biochem. Biophysiol., 121(2):177-184 (1998) (Abstract)	
	НЗ	Irwin et al., "The Xenopus Proglucagon Gene Encodes Novel GLP-1-Like Peptides with Insulinotropic Properties," Proc. Natl. Acad. Sci. USA, 94:7915-7920 (1997)	
	13	Mojsov, "Structural Requirements for Biological Activity of Glucagon-Like Peptide-I," Int. J. Pept. Protein Res., 40(3-4):333-343 (1992) (Abstract)	
	J3	O'Halloran et al., "Glucagon-Like Peptide-1 (7-36)-NH2: A Physiological Inhibitor of Gastric Acid Secretion in Man," J. Endocrinol., 126(1):169-173 (1990) (Abstract)	
	К3	Orskov et al., "Biological Effects and Metabolic Rates of Glucagonlike Peptide-1 7-36 Amide and Glucagonlike Peptide-1 7-37 in Healthy Subjects are Indistinguishable," Diabetes, 42(5):658-661 (1993) (Abstract)	

Examiner Signature	Date Considered	
		

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Subs	stitute for form 1449	В/РТО	JUL 0	1 2004 C	lete if Known	
					Application Number	10/741,534
INFORMATION DISCLOSURE Filing Date December 19, 2003 First Named Inventor Alain BARON	December 19, 2003					
					First Named Inventor	Alain BARON
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Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	A4	Raufman et al., "Truncated Glucagon-Like Peptide-1 Interacts with Exendin Receptors on Dispersed Acini from Guinea Pig Pancreas," J. Biol. Chem., 267(30):21432-21437 (1992)	
	B4	Ritzel et al., "A Synthetic Glucagon-Like Peptide-1 Analog with Improved Plasma Stability," J. Endocrinol., 159:93-102 (1998)	
1	C4	Schjoldager <i>et al.</i> , "GLP-1 (Glucagon-Like Peptide 1) and Truncated GLP-1, Fragments of Human Proglucagon, Inhibit Gastric Acid Secretion in Humans," <i>Dig. Dis. Sci.</i> , 34(5):703-708 (1989) (Abstract)	
•	D4	Wettergren et al., "Truncated GLP-1 (Proglucagon 78-107-amide) Inhibits Gastric and Pancreatic Functions in Man," Dig. Dis. Sci., 38(4):665-673 (1993) (Abstract)	
	E4	Willms et al., "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," J. Clin. Endocrinol. Metab., 81(1):327-332 (1996) (Abstract)	
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